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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,732	03/24/2004	Young-Min Kim	Q109250	4429

23373 7590 10/08/2008

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
10/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,732	KIM ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/08 has been entered.

Claims 1-20 and 22-24 are under consideration.

Applicant's arguments filed 7/14/08 have been fully considered but they are not persuasive.

The provisional rejection of claims 1-20 and 22-24 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/535,232 is withdrawn in view of the amendments. The co-pending claims recite a conjugate comprising an Fc fragment. Although the open language would embrace a whole immunoglobulin, the co-pending specification is clearly directed to fragments and does not fairly suggest using the whole immunoglobulin.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to recite "a whole immunoglobulin" and claim 18 has been amended to recite "one whole immunoglobulin."

As set forth in the Advisory Action mailed 6/26/08, applicant pointed to Figures 2 and 4 in support of the limitation "whole immunoglobulin." Figures 2 and 4 are with respect to a particular hGH-PEG-IgG construct of Example 1. This does not provide contemplation or disclosure of all conjugates now embraced by the claims. The concept of "whole immunoglobulins" is not generally disclosed in the specification. It is not clear what the metes and bounds of this phrase are. For example, it cannot be determined whether the recitation "whole immunoglobulin" include single chain antibodies, chimeric antibodies, humanized antibodies, and so forth. It cannot be determined if the claims are limited to only naturally occurring and intact immunoglobulins.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 and 11-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Heavner (US 2003/0211078).

This rejection is maintained for reasons of record.

Heavner discloses bifunctional molecules where PEG is bound at one end to a physiologically active polypeptide and at the other end to an immunoglobulin. The molecules have improved half life. The PEG has reactive groups at either end. Reactive groups specifically disclosed include maleimide and aldehyde. The PEG is linked to the amino terminal residue lysine or cysteine of the immunoglobulin or physiologically active polypeptide. The immunoglobulin can be an IgG, particularly IgG1. The proteins can be made recombinantly which would alter the nature of glycosylation depending upon the host cell in which it is produced. Physiologically active polypeptides include erythropoietin (EPO), cytokines such as tumor necrosis factor (TNF), blood proteins such as Factor VII. See abstract, figures, claims, Tables 1-4, Examples, paragraphs [0042, 0068-0075, 0086, 0091].

Note that at least paragraph [0019] includes whole immunoglobulins as well as fragments thereof. Whole immunoglobulins are not excluded by the disclosure of Heavner et al.

The molecules of Heavner et al. meet the structural and functional limitations of the claims. The claims do not require any particular amount or degree of increased half-life. The use of the term "comprising" permits the inclusion of additional components. The conjugate is not limited to only those components recited in the claims.

Claims 1-2, 9-10, 15-16, 18-20, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Mohamed et al. (US 2006/0153839).

This rejection is maintained for reasons of record.

Mohamed et al. claims priority to and is entitled to benefit of 60/411,731. The effective filing date of Mohamed et al. is 9/16/02 and as such is valid prior art against the instant application.

Mohamed et al. discloses bifunctional molecules where PEG is bound at one end to a physiologically active polypeptide and at the other end to an immunoglobulin. Mohamed et al. discloses conjugating to PEG via succinimide derivatives. Example 6.1 at page 23 uses the entirety of the monoclonal antibodies and not fragments thereof. The ratio of monoclonal antibody to PEG is 1:8. See paragraph [201]. Example 6.2 conjugates PEG to a first whole antibody at a molar ratio of 3:1 followed by separation via chromatography before further conjugating to the second single chain antibody fragment. See paragraph [228]. See also at least abstract, claims, and paragraphs [0112-0117].

The molecules of Mohamed et al. meet the structural limitations of the claims. PEG would have been well known at the time of the invention to increase in vivo half life (as is clear from the prior art of record) and as such, the bifunctional molecules of Mohamed et al. would inherently possess this feature absent evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa